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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ALBUMIN FUSION PROTEINS

(57) Abstract: The present invention encompasses albumin fusion proteins. Nucleic acid molecules encoding the albumin fusion proteins of the invention are also encompassed by the invention, as are vectors containing these nucleic acids, host cells transformed with these nucleic acids vectors, and methods of making the albumin fusion proteins of the invention and using these nucleic acids, vectors, and/or host cells. Additionally the present invention encompasses pharmaceutical compositions comprising albumin fusion proteins and methods of treating, preventing, or ameliorating diseases, disorders or conditions using albumin fusion proteins of the invention.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/40891

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C07K 1/00; C12P 21/04, 21/06; A01N 37/18; G01N 31/00
US CL : 530/350, 362; 435/69.1, 69.7; 514/2; 436/15, 18

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 530/350, 362; 435/69.1, 69.7; 514/2; 436/15, 18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
West & East (US patents, US published applications, EPO, JP), interferon, hybrid, fusion, albumin

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,959,075 A (LOK et al.) 28 September 1999 (28.09.1999), col. 17, lines 35-45; col. 15, lines 5-15 and 40-45; col. 21, lines 28-53; claim 6.	1, 3-12, 17, 18, 20, 21
X — Y	WO 97/24445 A1 (DELTA BIOTECHNOLOGY LIMITED) 10 July 1997 (10.07.1997), abstract, page 3, lines 25-30, page 4, lines 29-30, page 24, lines 15-22, page 10, lines 5-20, page 5, lines 4-27, page 12, lines 13-21, page 13, lines 23-30	1-12, 14, 17-21 — 13, 15, 16
Y	US 5,668,007 A (SPENCER et al.) 16 September 1997 (16.09.1997), col. 10, lines 57-60.	1, 16
Y	US 6,300,065 B1 (KIEKE et al) 09 October 2001 (09.10.2001), col. 42, lines 35-40.	1, 13, 15, 16

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer Laurie Mayes Telephone No. (703) 308-0196

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BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Groups 1-97, claim(s) 1-21, drawn to a fusion protein comprising a therapeutic protein X, wherein X corresponds to values found in Table 1, and albumin or a fragment thereof.

Groups 98-194, claim(s) 22-25, drawn to a method of treating a disease comprising administering a fusion protein comprised of X, wherein X corresponds to values found in Table 1, and drawn to a fusion protein comprising a therapeutic protein X, wherein X corresponds to values found in Table 1, and albumin or a fragment thereof.

Groups 195-291, claim 26, drawn to a method of extending the shelf life of a fusion protein comprising X, wherein X corresponds to values found in Table 1, and albumin or a fragment thereof.

Groups 292-388, claim(s) 27-29, drawn to a nucleic acid molecule comprising a polynucleotide sequence encoding a fusion protein comprised of X, wherein X corresponds to values found in Table 1, and albumin or a fragment thereof, and a vector and host cell comprising the nucleic acid molecule.

The inventions listed as Groups 1-388 do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The polynucleotides and polypeptides of each of the molecules in Table 1 are unrelated each to each other. The polynucleotide sequences encode structurally distinct polypeptides and do not share a special technical feature. Furthermore, the technical feature that links the nucleotides, protein and methods of treating disease and extending the life of the protein, namely, a fusion protein comprising the therapeutic protein insulin (Table 1, page 21) and albumin is known in the art (US 5,959,075, col. 17, lines 35-45). Thus, the groups lack a common special technical feature and lack unity of invention under PCT Rules 13.1-13.2.